Version with markings showing changes made

In the specification

Pages 1 and 19-21 showing changes made AND
new corrected pages 1 and 19-21 are submitted herewith.

In the claims:

Claims 1, 10, and 21 have been amended as follows"

1.(Amended) A device for monitoring **[an oxidizing vapor or]** plasma comprising:

at least one layer of polymer, having incorporated therein

a) an indicator capable of undergoing at least one color change

b) an activator for said indicator wherein said activator, when contacted with said **[oxidizing vapor or]** plasma, undergoes a reaction wherein the product of said reaction causes said indicator to undergo said color change.

10.(Amended) The device of Claim 1 wherein said polymer is a polymer of **[styrene,]** acrylate, acrylic acid, acrylamide, vinyl acetate, vinyl alcohol, vinyl chloride, styrene, polyurethanes, cellulose nitrate, carboxymethyl cellulose or a mixture thereof.

21.(Amended) The device of claim 1 wherein said activator is a salt of an amine and an organic or inorganic acid **[acid]**.

New Claims 42-49 have been added as follows:

42. (New) A device for monitoring hydrogen peroxide plasma comprising:

at least one layer of polymer, having incorporated therein

a) an indicator capable of undergoing at least one color change

an activator for said indicator wherein said activator, when contacted with said plasma, undergoes a reaction wherein the product of said reaction causes said indicator to undergo said color change.

43. (New) The device of claim 42 wherein said polymer is soluble in water or is water dispersible.

44. (New) The device of claim 43 wherein said polymer is a water soluble or water dispersable homopolymer, or a copolymer or a mixture thereof.

45. (New) The device of Claim 43 wherein said polymer is a polymer of acrylate, acrylic acid, acrylamide, vinyl acetate, vinyl alcohol, vinyl chloride, styrene, polyurethanes, cellulose nitrate, carboxymethyl cellulose or a mixture thereof.

46. (New) The device of claim 45 wherein the polymer is an acrylate polymer.

47. (New) The device of claim 45 wherein the polymer is cellulose nitrate or carboxymethylcellulose.

48. (New) A process of making a device of claim 42 which comprises dissolving or dispersing the components thereof in a solvent therefor, applying the thus formed solution or dispersate to a substrate and permitting the solvent to evaporate.

49. (New) A process of using a device of claim 42 for monitoring sterilization of materials comprising the steps of

a) affixing the device to said materials or containers containing same

b) carrying out the process of sterilization including the step of introducing hydrogen peroxide plasma into a vessel containing said materials or containers therefore and

c) observing the presence of a color change of said device.

TITLE OF THE INVENTION

Indicators for monitoring sterilization with plasma

RELATED APPLICATION

This application claims priority of Provisional Application 60/129,130 filed 13 April 1999 and PCT/US00/09493 filed 11 APRIL 2000

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates to chemical indicators for monitoring plasmas, in particular for sterilization of medical supplies with in particular that from hydrogen peroxide.

2. BRIEF DESCRIPTION OF PRIOR ART

A wide variety of medical supplies and biological wastes are sterilized with materials and techniques, such as steam, ethylene oxide (ETO), high energy radiation and plasma. It is essential to assure that these supplies or wastes are actually sterilized. A number of indicators, dosimeters and monitors have been proposed in the literature. They include biological and chemical indicators. The color changing chemical indicators are inexpensive and hence are widely used.

In order to assure the sterilization with plasma has taken place, the indicator must determine integral value of parameters, such as time, temperature, humidity, and concentration of the plasma gas. Biological indicators made from cultures, such as Bacillus subtilis spores, bacillus pumilus spores and clostridium sporogenes spores have been used for monitoring the sterilization, for example, US patents 5,801,010, 5,788,925, and 5,866,356. However, chemical indicators are preferred because they are simple and inexpensive.

W09846994A1 and W09846279A1 describe compositions comprising dyes and organic amines which change color when contacted with hydrogen

required for the color change. The time required for the color change can also be varied by selecting proper indicators, activators, polymers and their mixtures.

For a given sterilization cycle, the time required for the color change can be varied by varying one or more of the following parameters:
w/w = weight to weight percent

1. **Thickness of the polymer indicator layer**.

The thickness of the indicator and barrier layers may vary from a micron to a few hundred microns. The preferred thickness is 1-50 microns and the most preferred range is 2-20 microns.

2. **Concentration of the activator** .

The concentration of activator may vary from 0.1 to 50 w/w%. The preferred concentration is 1 to 20 w/w% and the most preferred concentration is 2-10 w/w/%.

3. **Concentration of the indicator.**

The concentration of the indicator may vary from 0.1 to 20w/w%. The preferred concentration is 10 to 10w/w% and the most preferred concentration is 2-5 w/w%.

4. **Concentration of other additives**.

The concentration of additives may vary from 0.1 to 20w/w%. The preferred concentration is 0.5 to 10w/w% and the most preferred concentration is 1-5w/w/%.

[5. **Nature of the polymer**]

5. [6]. **Nature of the barrier**

This is the same group as the polymer, but may be different from it

6. [7]. **Thickness of the barrier**

The barrier may be between 2 and 200 microns thick, preferrably 2-20 microns.

[8. **Nature of the activator**

9. **Nature of the indicator]**

7. [10. **Nature of the additives]** **Sterilization time range**

The preferred time range for sterilization is from 5 minutes to a few hours, The most preferred time is about 15-60 minutes.

In addition to the plasma of hydrogen peroxide, the device may be used with other plasmas, such as that of peracetic acid and a mixture of hydrogen, oxygen and argon, as well as for hydrogen peroxide itself.

Advantages: The plasma indicator disclosed here offers the following advantages:

*. It is selective to plasma (i.e., no or least effect of other sterilants).

*. It provides desired color changes (from a starting light color, such as white/colorless, yellow, orange, pink, or red to a final dark color, such as blue, green, black, purple or violet).

*. It provides an intermediate color for monitoring a partial cycle.

*. The time, temperature etc required for the color change can be varied by simple means.

*. There is essentially no effect of ambient conditions (e.g., dry heat, humidity and light) before and after the sterilization.

*. It is unaffected by sealing hot bar.

*. It has required pot life.

*. There is no bleeding/diffusion of dyes.

*. The ingredients (indicators/dyes and activators/additives) are water soluble. No grinding of ingredients required.

*. Formulations can be made by simple procedures (mixing/dissolution).

*. Ink is printable with gravure and flexo presses on polyester, paper and Tyvek.

*. The print rolls are easy to clean.

*. It uses least toxic or hazardous chemicals.

*. It uses readily available chemicals (dyes, activators and binders).

*. There is an option of precision measurement with moving boundary.

*. Formulations are inexpensive.

*. It is unaffected by ethylene oxide, steam, heat and radiation.

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